REMARKS

The Requirement for Restriction has been carefully reviewed. It is the Examiner's position that the present claims encompass fourteen (14) groups of inventions. These are as follows:

Group I: Claims 2,3, 5, 7, 9-12, and 15-16 drawn to a peptide of the amino acid sequence depicted as SEQ ID NO: 1 and a method for treating CNS damage comprising administering the peptide of SEQ ID NO: 1;

Group II: Claims 2,3, 5, 7, 9-12, and 15-16 drawn to a peptide of the amino acid sequence depicted as SEQ ID NO: 3 and a method for treating CNS damage comprising administering the peptide of SEQ ID NO: 3;

Group III: Claims 18-21, drawn to a method of designing a mimetic of a peptide depicted as SEQ ID NO: 1;

Group IV: Claims 18-21, drawn to a method of designing a mimetic of a peptide depicted as SEQ ID NO: 3;

Group V: Claim 22 drawn to a bacteriophage which expresses a fusion protein consisting of the peptide of SEQ ID NO: 1;

Group VI: Claim 22 drawn to a bacteriophage which expresses a fusion protein consisting of the peptide of SEQ ID NO: 3;

Group VII: Claims 23-25 drawn to a screening method for identifying peptides capable of binding to Nogo, MAG, and/or TN-R, comprising using a bacteriophage which expresses a fusion protein consisting of the peptide of SEQ ID NO: 1;

Group VIII: Claims 23-25 drawn to a screening method for identifying peptides capable of binding to Nogo, MAG, and/or TN-R, comprising using a bacteriophage which expresses a fusion protein consisting of the peptide of SEQ ID NO: 3;

Group IX: Claim 26, drawn to a method of searching for factors which reduce the inhibitory effect of TN-R, MAG, and/or Nogo, comprising interrogating a sequence database to identify polypeptides that comprises SEQ ID NO: 1;

Group X: Claim 26, drawn to a method of searching for factors which reduce the inhibitory effect of TN-R, MAG, and/or Nogo, comprising interrogating a sequence database to identify nucleic acids that encode the polypeptide of SEQ ID NO: 1;

Group XI: Claim 26, drawn to a method of searching for factors which reduce the inhibitory effect of TN-R, MAG, and/or Nogo, comprising interrogating a sequence database to identify polypeptides that comprises SEQ ID NO: 3;

Group XII: Claim 26, drawn to a method of searching for factors which reduce the inhibitory effect of TN-R, MAG, and/or Nogo, comprising interrogating a sequence database to identify nucleic acids that encode the polypeptide of SEQ ID NO: 3;

Group XIII: Claim 27, drawn to a method of searching for factors which reduce the inhibitory effect of TN-R, MAG, and or Nogo, comprising screening a cDNA library with an oligonucleotide probe that hybridizes with a nucleic acid encoding SEQ ID NO: 1; and

Group XIV: Claim 27, drawn to a method of searching for

factors which reduce the inhibitory effect of TN-R, MAG, and or Nogo, comprising screening a cDNA library with an oligonucleotide probe that hybridizes with a nucleic acid encoding SEQ ID NO: 3.

It is the Examiner's position that the inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1, because, under PCT Rule 13.2, they lack the same or corresponding special technical feature.

Applicants respectfully assert that the restriction requirement set forth above is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty.

As stated in § 1893.03(d) of the M.P.E.P.:

> Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. § 371...
>
> The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.
>
> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art....

The special technical feature linking these claims is the discovery that the peptides disclosed interact with the inhibitory domains of the myelin proteins Nogo, TNR and MAG and thus are useful for the treatment of CNS damage. Exemplary peptides include SEQ ID NOS: 1 and 3.

The requirements of the PCT are, of course, supposed to take precedence over normal national practice for the national phase of a PCT application. In particular, it is not permissible under the PCT for national offices to require compliance with the requirements relating to the form or contents of the application different from or additional to those which are provided for in the PCT (Art 27 PCT). In this specific instance, the PCT Handbook says at section 33.35, paragraph 2 "a designated office ought not to raise an objection as to a lack of unity when the International Searching and/or Preliminary Examining Authority has found that the claims comply with the requirement for unity of invention". Indeed, the PCT Contracting States have agreed to this principle, according to the PCT Handbook at Section 23.9 paragraph 2 (which refers to the report of the PCT assembly, 18th session (1991), item 24).

Notably, during the international stage of this application, the Examiner **did not** make a lack of unity finding and considered all of the claims to be directed to a single invention.

The Examiner has stated that the polypeptide and a bacteriophage encoding said polypeptide as part of a fusion with a bacteriophage coat protein are different inventions, because a polypeptide and a bacteriophage are completely different products. However, Applicant respectfully submits that this is incorrect, because these claims have corresponding special technical features. The claims are analogous to claims to a protein and a nucleic acid, which despite being chemically and structurally different products

are expressly acknowledged to be unified under the PCT by virtue of the fact that the claimed DNA molecule encodes the protein (see example 39 contained in chapter 10 of the International Search and Preliminary Examination Guidelines).

With regard to the method claims, the Examiner has pointed to the fact that the various methods comprise using different steps and products. However it is clear from the section of the MPEP cited above that unity of invention requires only one shared or corresponding special technical feature. This is provided by sequence of SEQ ID NO:1.

Group III, for example, involves the step of analysing the protein of SEQ ID NO:1.

The methods of group VII employ a bacteriophage expressing a protein of SEQ ID NO:1 on its surface.

The methods of Group IX comprise identifying proteins which comprise SEQ ID NO:1, and the methods of group X comprise identifying nucleic acids which comprise a nucleic acid sequence encoding SEQ ID NO:1. Again, it is noted that a protein and nucleic acid sequence are expressly considered to be corresponding technical features under unity practice. For the purposes of assessing unity under the PCT, it is irrelevant that the search may involve looking in different databases.

Claim 27 similarly relates to a method of identifying nucleic acids encoding SEQ ID NO:1, comprising screening a cDNA library with a suitable oligonucleotide probe.

Moreover, Groups III, VII, IX, X and XIII are also unified by the inventive concept that a polypeptide comprising SEQ ID NO:1 or a mimetic thereof will bind Nogo, MAG and/or TN-R.

Hence, all of groups I, III, V, VII, IX, X and XIII are unified. Accordingly, withdrawal, or at the very least modification of the restriction requirement is in order.

Plainly, the written restriction requirement fails to

comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under § 371. It is unclear how the Examiner could conclude that instant application now has fourteen Groups of inventions, when the international application from which it originates has unity of invention.

Finally, according to the MPEP §803.01, there are two criteria for restriction between inventions which are alleged to be patentably distinct: 1) the inventions must be independent and distinct as claimed and 2) there must be a serious burden on the Examiner if the restriction is not required.

The MPEP at §802.01 defines the terms "independent" and "distinct" as:

INDEPENDENT

> The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process.

DISTINCT

> The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use, or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior art). It will be noted that in this definition the term related is used as an alternative for dependent in referring to subjects other than independent subjects.

Notwithstanding the Examiner's assertion to the contrary, it is apparent from an objective reading of the claims corresponding to the Group I, III, V, VII, IX, X and XIII inventions that they are drawn to closely related subject matter and, therefore, do not comprise separate and distinct

inventions. Nor can the examination of these Groups of invention together reasonably be regarded as imposing a serious burden on the Examiner. Indeed, each of these groups of invention are directed to SEQ ID NO: 1 or a method of using SEQ ID NO: 1. Accordingly, the above-mentioned Groups cannot be properly determined to be "independent."

Finally, while the United States Patent and Trademark office has a legitimate interest in obtaining proper revenue from filing and issuance fees, it does not have the unrestrained power to tax inventors. The Applicants are entitled to obtain patent protection on each novel aspect of the invention, namely peptides which bind inhibitory domains of certain myelin proteins and methods of use thereof. If Applicants are forced to divide this application into fourteen (14) separate patent applications as a result of the restriction requirement imposed by the Examiner, the Applicants will be unduly and unfairly burdened with excessive fees and cost associated with the prosecution and maintenance of multiple (as contrasted to a single) patents.

For all of the foregoing reasons, Applicants respectfully request withdrawal, or at the very least a modification of the present restriction requirement.

In order to be fully responsive to the above-mentioned requirement, Applicants hereby elect, with traverse, Group I, claims 2,3, 5, 7, 9-12 and 15-16 drawn to a peptide of the amino acid sequence shown in SEQ ID NO: 1 and method of treating CNS damage comprising administration of said peptide. Applicants also respectfully request that the Examiner consider searching claims reading on SEQ ID NO: 3, namely Group II, IV, VI, VIII, XI, XII, XIV as the SEQ ID NOS: 1 and 3 peptides are particularly preferred for use in methods for the treatment of CNS damage.

Applicants reserve the right to file one or more continuing applications under 35 U.S.C. §120 on the subject

matter of any claims finally held withdrawn from consideration in this application.

Favorable consideration leading to prompt allowance of the present application is respectfully requested.

Respectfully submitted,
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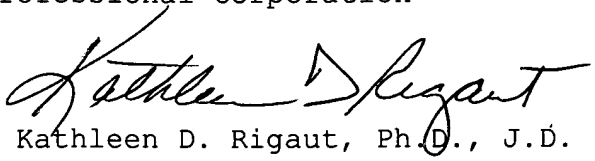
By 
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